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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/149,721	09/08/1998	RUSS J. MUMPER	237/023	5410

34055 7590 07/02/2004

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EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/149,721

Applicant(s)

MUMPER ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9 and 41-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-9 and 41-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

Response to Amendment

Response to Election of Species

Applicant's election with traverse of Species 1 in Paper No. 19 is acknowledged. The traversal is on the ground(s) that compositions contain common compounds, i.e., lipids, polynucleotide analogs, etc. This is not found persuasive because the election requirement was not based on a restriction of groups but rather distinct species, wherein each species has acquired a separate status in the art and requires a divergent search. An action on the merits of claims 1, 7-9 and 41-86 are set forth below.

The requirement is still deemed proper and is therefore made FINAL.

New Matter

The amendment filed 4-26-2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The addition of a negative proviso for the R₅' variable. Applicant submitted an amendment to the specification and claims in response to the office action mailed 10/26/00; wherein the negative proviso was added (pp. 3-4); however, it is clear that the proviso was not set forth in the original specification, nor is there any data that applicant contemplated this proviso at the time of filing. The original specification does not modify the R₅' variable based on conditions present with the R₃' and R₄' variables; moreover, there is no evidence that applicant contemplated a compound wherein the relevant species contained provisional language that recognized compounds of the prior art and excluded the instant compounds from those species.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

35 USC 112(1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 is drawn to a negative proviso for R₅; however it is noted that this proviso was not supported by the original specification. Applicant submitted an amendment to the specification and claims in response to the office action mailed 10/26/00; wherein the negative proviso was added; however, it is clear that the proviso was not set forth in the original specification, nor is there any data that applicant contemplated this proviso at the time of filing. The original specification does not modify the R₅ variable based on conditions present with the R₃ and R₄ variables; moreover, there is no evidence that applicant contemplated a compound wherein the relevant species contained provisional language that recognized compounds of the prior art and excluded the instant compounds from those species.

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35 USC 112(2)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59- 65 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 recites the limitation "having an effective diameter between 100 and 300 nanometers" in claim 42. There is insufficient antecedent basis for this limitation in the claim. The diameter limitation in claim 59 is directed toward that of spherical or cylindrical particles wherein there is no particle shape actually set forth in the composition of claim 42. Accordingly, dependent claims 60-65 are rejected as they fail to obviate the rejections set forth in the parent claim(s).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Boullanger et al., *Carbohydrate Research*, vol. 278, 1995, pp. 91-101 or Miyajima et al., EP 457910 A1.

Claim 1 is drawn to a compound comprising a glycosyl moiety having a nitrogen based substituent linked to a carbon atom within said glycosyl moiety, wherein said nitrogen-based substituent is selected from the group consisting of -NH₂, -N⁺(CH₃)₃, - (CH₂)_n-N(R₁₀)₃, -NH-C(N+H₂)-NH₂; wherein substituents linked to other carbon atoms

within said glycosyl moiety are independently selected from the group consisting of hydrogen, alkyl, -O-alkyl and various other carbonyl and amine based substituents.

Boullanger et al. anticipates this claim as it teaches an alkylated glycosylamine analogous to that set forth in the claims cited supra (p. 95, scheme 2, step ii).

In claim 1, wherein R_5 is O-C-O-alkyl and R_1' is alkyl, Myajima anticipates the claim as it teaches an alkylated glucosamine methylglycoside (p. 11, lines 15-50).

Applicant's have amended the claim 1 with a proviso to overcome the prior art of record; however, as cited supra, the negative proviso is not supported by specification, thus the 35 U.S.C. 102(b) rejection of record stands.

Claims 41 and 50 are rejected under 35 U.S.C. § 102(b) as being anticipated by Male-Brunne et al. (Male-Brunne), WO 96/24334.

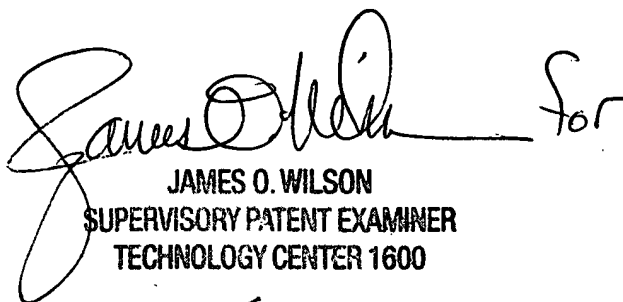
Claims 41 is a composition claims wherein a glycosyl moiety is substituted with a nitrogen based substituent selected from the group consisting of $-NH_2$ and a polynucleotide. Dependent claim 50 is drawn to the polynucleotide selected from a polynucleotide analogue.

Male-Brunne anticipates the claims as it teaches a aminoglycoside substituted with cholesterol, (see abstract and p.12, lines 28-31) in composition with a polynucleotide, see p. 4, lines 29-32.

Claims 7-9, 42-49, 51-86 appear to contain subject matter allowable over the prior art of record.

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Howard V. Owens
Patent Examiner
Art Unit 1623

 for
JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Samuel Barts
Primary Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.